

Research and Special Programs

Administration

400 Seventh Street, S.W. Washington, D.C. 20590

SEP 2 2 2004

DOT-E 13208 (FIRST REVISION)

EXPIRATION DATE: April 30, 2005

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE:

Provensis Limited of South Harefield South Harefield, Middlesex, United Kingdom (U.S. Agent: Provensis Inc., West Conshohocken, PA)

2. PURPOSE AND LIMITATION:

- a. This exemption authorizes the transportation in commerce of certain DOT Specification 2Q containers containing only a Division 2.2 material for use in medical treatment. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
- b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.302a(a)(1) in that DOT Specification 2Q containers are not authorized for the material listed in paragraph 6, except as specified herein; Part 172 Subpart E unless transported by air; Part 172 Subpart F; Part 174; and Part 177 except for § 177.817.

- 5. BASIS: This exemption is based on Provensis Limited's application dated February 19, 2003, submitted in accordance with § 107.105 and the public proceeding thereon and additional information dated June 4, 2003.
- 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Oxygen, compressed	2.2	UN1072	N/A

7. SAFETY CONTROL MEASURES:

- a. <u>PACKAGING</u> Packagings prescribed are seamless DOT Specification 2Q containers not exceeding 500ml capacity and having a minimum burst pressure of 270 psig. Containers must be shipped as follows:
 - (1) The pressure in the container shall not exceed 75 psig at 70° F and 90 psig at 130° F.
 - (2) The containers must be packed in strong outside packagings.
 - (3) Each package shall not exceed 66 pounds gross weight.
- b. TESTING Each completed container filled for shipment must have been heated until the pressure in the container is equivalent to the equilibrium pressure of the content at 130°F without evidence of leakage, distortion, or other defect.
- c. <u>OPERATIONAL CONTROLS</u> Shipments are not subject to the labeling requirements of Subpart E of Part 172 except when offered for transportation by air. Shipments are not subject to the placarding requirements of Subpart F of Part 172; to Part 174 and to Part 177, except for § 177.817.

8. SPECIAL PROVISIONS:

- a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modifications or change are made to the package and it is reoffered for transportation in conformance with this exemption and the HMR.
- b. A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.
- c. Each outer package must meet the marking requirements of Subpart D of Part 172 and be marked "DOT-E 13208".
- d. This exemption does not authorize reclassification as Consumer commodity, ORM-D.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, and cargo aircraft only.
- 10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each aircraft used to transport packages covered by this exemption. The shipper must furnish a copy of this exemption to the air carrier before or at the time the shipment is tendered.
 - (1) A maximum of 20 packages of 20 authorized containers each may be carried aboard each aircraft.
 - (2) Packages of authorized containers must not be loaded in an inaccessible cargo location on a cargo-only aircraft. Packages must be loaded in such a manner that a crew member or other authorized person can see, handle and when size and weight permit, separate such packages from other cargo during flight.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 <u>et seq</u>:
 - o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (Sections 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued in Washington, D.C.:

n Robert A. McGuire

Associate Administrator for Hazardous Materials Safety

sociate Administrator for

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(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590. Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/exemptions. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: CWF/dl